IUCLID

Data Set

Existing Chemical	:	ID: 26741-53-7
CAS No.	:	26741-53-7
EINECS Name	:	3,9-bis(2,4-di-tert-butylphenoxy)-2,4,8,10-tetraoxa-3,9-diphosphaspiro[5.5]undecane
EC No.	:	247-952-5
Molecular Formula	:	C33H50O6P2

Producer related part

Company	:	Epona Associates, LLC
Creation date	:	03.01.2007

Substance related part

Company	:	Epona Associates, LLC
Creation date	:	03.01.2007
Status	:	
Memo	:	Ultranox 626
Printing date	:	10.01.2007
Revision date	:	
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Number of pages	:	2
Chapter (profile)	:	Chapter: 5
Reliability (profile)	:	Reliability: without reliability, 1, 2, 3, 4
Flags (profile)	:	Flags: without flag, confidential, non confidential, WGK (DE), TA-Luft (DE), Material Safety Dataset, Risk Assessment, Directive 67/548/EEC, SIDS

5.0 TOXICOKINETICS, METABOLISM AND DISTRIBUTION

5.1.1 ACUTE ORAL TOXICITY

5.1.2 ACUTE INHALATION TOXICITY

5.1.3 ACUTE DERMAL TOXICITY

5.1.4 ACUTE TOXICITY, OTHER ROUTES

5.2.1 SKIN IRRITATION

5.2.2 EYE IRRITATION

5.3 SENSITIZATION

5.4 REPEATED DOSE TOXICITY

5.5 GENETIC TOXICITY 'IN VITRO'

5.6 GENETIC TOXICITY 'IN VIVO'

5.7 CARCINOGENICITY

5.8.1 TOXICITY TO FERTILITY

Type	:	other
Species	:	rat
Sex	:	male/female
Strain	:	other: Charles River CD
Route of admin.	:	oral feed
Exposure period	:	90 days
Frequency of treatm.	:	daily
Premating exposure period		
Male	:	
Female	:	
Duration of test	:	90 days
No. of generation studies	:	1
Doses	:	100, 300 and 1000 ppm

hair loss. missing or malaligned upper incisor, excessive lacrimation, red material around the eyes, leaning to left, red or swollen eyes, rales, cornea1 opacity, swollen ventral neck, swollen conjunctiva and dilated pupil.

Ophthalmologic findings: There were no compound related effects noted during the 3-month ophthalmic examinations.

Hematology: No compound related effects on the results of the hematologic tests were observed.

Clinical biochemistry: No compound related effects on the results of the biochemical tests were observed.

Mortality: No compound related effects on survival rates were noted (one female rat in the 1000 ppm group died during the study).

Gross pathology: No compound related gross lesions were observed in any of the rats from the treated groups. No tumors were noted upon gross examination. There were no macroscopic changes for any of the reproductive organs exmained.

Organ weight changes: Statistically significant variations ($p<0.01$) in absolute weights of kidneys of male rats at 300 ppm and hearts of male rats at 100 and 300 ppm were not considered compound related. There were no organ weight changes for any of the reproductive organs exmained.

Histopathology: Microscopic lesions considered probably compound related were seen in livers and spleens of the female rats from the 1000 ppm group. This consisted of very slight to slight extramedullary hematopoiesis in these organs. This lesion was not present in rats from the control and the 300 ppm groups but was seen in one rat from the 100 ppm group. Other microscopic lesions in livers and those seen in other organs in the control and 1000 ppm groups were considered spontaneous in nature and unrelated to the administration of the compound. There were no microscopic effects on any of the reproductive oragns exmained.

Test substance : Chemical name: 2,4,8,10-tetraoxa-3,9-diphosphaspiro [55]undecane, 3,9-bis[2,4-bis(l,l-dimethylethyl)phenoxy]-
CAS No.: 26741-53-7
Trade name: Weston XR-1532
Lot No.: 225-35
Impurities: 1% tris-isopropanolamine

Reliability : (2) valid with restrictions
Well conducted study, prior to GLP

10.01.2007 (1)

5.8.2 DEVELOPMENTAL TOXICITY/TERATOGENICITY

5.8.3 TOXICITY TO REPRODUCTION, OTHER STUDIES

5.9 SPECIFIC INVESTIGATIONS

5. Toxicity

Control group	:	yes, concurrent vehicle
NOAEL parental	:	1000 - ppm
Method	:	other: IRDC method
Year	:	1979
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4

Method : The test substance was fed in the diet to three groups of 20 male and 20 female rats. The rats were observed daily for signs of overt toxicity and mortality . Detailed observations including incidence, size and location of palpable masses and individual body weights were recorded weekly. Individual food consumptions were recorded daily. All rats received the ophthalmic examinations during the pretest period and at 3 months of study. Clinical laboratory test were performed for 10 rats/sex/group at 1 and 3 months of study.

Statistical methods: All statistical analyses compared the treatment groups with the control group by sex. Body weights, food consumption, absolute and relative organ weights and hematology, biochemistry and urinalysis parameters were compared by analysis of variance (one-way), Bartlett's test for homogeneity of variances and the appropriate t-test (for equal or unequal variances) as described by Steel and Torrie using Dunnett's multiple comparison tables to judge significance of differences.

Test subjects:
Weight at study initiation: 80-1079 (male), 77-989 (female) No. of animals/sex/dose: 20 male, 20 female

Study Design: Vehicle: Feed (Rodent Laboratory Chow)

Clinical observations performed and frequency: The rats were observed twice daily for signs of overt toxicity and mortality. Detailed observations were recorded weekly and included the size, incidence and location of all palpable masses. Individual body weights were recorded weekly and individual food consumption was recorded daily.

Organs examined at necropsy: The following tissues from 10 males and 10 females from the control group and the 1000 ppm group were examined microscopically: adrenals, aorta, eye and optic nerve, esophagus, stomach, duodenum, jejunum, ileum, cecum, colon, rectum, liver, trachea, spleen, pancreas, urinary bladder, bone marrow (sternum), prostate/uterus, seminal vesicles, testes/ovaries, brain, heart, lung and bronchi, sciatic nerve, pituitary, thyroid and parathyroid, mesenteric lymph node, mandibular lymph node, spinal cord, salivary gland (submaxillary), skeletal muscle (thigh), skin, mammary gland, thymus, kidneys, any other tissue with gross lesions.

Bone marrow smears from all rats were made at necropsy and examined microscopically. Additionally, livers and spleens from 10 male and 10 female rats from the 100 ppm and 300 ppm groups were examined.

Result : Body weight: The group mean body weights of both the low and mid dose male and female rats were greater than control values, and both groups of high dose males and females had group mean body weights lower than controls.

Food/water consumption: Low and mid dose male rats consumed slightly more food than did controls, while high dose males ate slightly less than control. All of the groups of females consumed approximately equivalent amounts of food.

Clinical signs: No signs of overt toxicity were observed among the treated rats. Incidental signs observed for a few control and/or treated rats included

9. References

(1) International Research and Development Corporation (1979), 90 day oral toxicity study in rats, Report No. 433-001

5.10 EXPOSURE EXPERIENCE

5.11 ADDITIONAL REMARKS